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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,108	04/08/2004	Mihrimah Ozkan	034044.030 (2003-368-2)	8315

53498 7590 10/20/2005

SMITH, GAMBRELL & RUSSELL, LLP (UC)
SUZANNAH K. SUNDBY
1850 M. STREET NW
800
WASHINGTON, DC 20036

EXAMINER

YU, MELANIE J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,108

Applicant(s)

OZKAN ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-14 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-15 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 29 July 2005 has been entered. Claims 2-4 and 15-21 are canceled. Claims 1, 5, 7, 14, 25, and 32 are currently amended. Claims 1, 5-14 and 22-36 are currently pending in this application. Claims 22-24 and 26-30 have been withdrawn from consideration.

Withdrawn Rejections

2. Previous rejections under 35 USC 102(b) and 35 USC 102(e) have been withdrawn in light of applicant's amendments. Previous rejections under 35 USC 112, second paragraph have been withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 8, 12-14, 25 and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Giaever et al. (US 5,187,096).

Giaever et al. teach a single reactant component which is a cell immobilized directly to a single electrode (col. 2, lines 53-59), wherein the electrode is gold (col. 5, lines 29-31).

Regarding claims 12 and 13, Giaever et al. teach the electrode placed on a substrate of a polymer (substrate, col. 5, lines 38-42; polystyrene, col. 5, lines 25-27 and 54-60).

With respect to claims 14 and 25, Giaever et al. teach a plurality of single reactant components immobilized directly to the single electrode (20 cells, col. 2, lines 64-68) and a biosensor comprising the single reactant component immobilized directly to the electrode (col. 11, lines 49-51).

Regarding claims 31-36, Giaever et al. teach a second single reactant component immobilized over a second single electrode (3 electrodes total 24, Fig. 2; electrodes have immobilized cells, col. 5, lines 11-17), wherein the second single reactant component is the same or different from the single reactant component, and a plurality of single reactant components immobilized over single electrodes, wherein the single reagent components may be the same or different (col. 8, lines 3-14). Giaever et al. also teach a substrate comprising a polymer upon which the single electrode is placed or immobilized (col. 5, lines 25-27). Giaever et al. teach the biosensor further comprising a reaction chamber (col. 5, lines 54-60, cylindrical hole creates reaction chamber 20, Fig. 1, 2).

2. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al. (US 5,328,843).

Fukuda et al. teach a neuron immobilized directly to a single electrode (Figs. 9 and 10; col. 13, line 47-col. 14, line 28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaever et al. (US 5,187,096) in view of Hobbs et al. (US 4,160,205).

Giaever et al. teach a cell immobilized directly to a single electrode, but fail to teach the immobilized single reactant component being a microorganism of *E. coli*.

Hobbs et al. teach the cell activity of a microorganism of *E. coli* detected between electrodes (col. 3, line 66-col. 4, line 6).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as a single reactant component immobilized to the electrode of Giaever et al., a microorganism of *E. coli* as taught by Hobbs et al., in order to provide detection of rapid motions of cells and provide identification of activity of single cells.

4. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaever et al. (US 5,187,096).

Giaever et al. teach a cell immobilized directly to a single electrode having an area of 10^{-2} - 10^{-4} cm² (col. 5, lines 50-53), but fail to teach a specific diameter of a single electrode.

However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of

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an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claims 9-11 are for any particular purpose or solve any stated problem, and the prior art teaches that the dimensions of an electrode can be altered in order to adjust sensitivity of an electrode to provide an electrode with increased sensitivity for a single cell, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the electrode art.

Response to Arguments

5. Applicant's arguments with respect to claims 1, 5-14, 25 and 31-36 have been considered but are moot in view of the new ground(s) of rejection made in view of applicant's amendment to claim 1 requiring a new limitation of a single reactant component immobilized directly to an electrode.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/14/05